K024192

JUN 11 2003

# 510 (k) Summary of Safety and Effectiveness for VectorVision® Fluoro3D

**Manufacturer:**


| | |
|---|---|
| Address: | BrainLAB AG<br>Ammerthalstrasse 8<br>85551 Heimstetten<br>Germany<br>Phone: +49 89 99 15 68 0<br>Fax: +49 89 99 15 68 33 |
| Contact Person: | Mr. Rainer Birkenbach |
| Summary Date: | February 12, 2003 |


**Device Name:**

| | |
|---|---|
| Trade name: | VectorVision® Fluoro3D |
| Common/Classification Name: | VectorVision, BrainLAB Image Guided Surgery System / Instrument, Stereotaxic |

**Predicate Device:**
**Vector Vision®** 2 (K983831)
**Vector Vision® Spine** (K981508)
**Vector Vision® CT/Fluoro** (K010968)

Device Classification Name: Instrument, Stereotaxic
Regulatory Class: Class II

**Intended Use:**
BrainLAB VectorVision® Fluoro3D is intended to be an intraoperative image guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative image data being processed by a VectorVision workstation. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-ray or MR based model of the anatomy.

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Example procedures include but are not limited to:

Spinal Procedures:
- Spinal implant procedures as pedicle screw placement.

**Device Description:**
VectorVision® Fluoro3D intends to enable "touchless" patient registration for operational planning and navigation in surgery. It allows using automatic registered intra-operatively acquired image modalities (e.g. volume data calculated from a set of x-ray images) processed by a VectorVision workstation.

**Substantial equivalence:**
VectorVision® Fluoro3D Module has been verified and validated according to BrainLAB's procedures for product design and development. The validation proves the safety and effectiveness of the system. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with the predicate device VectorVision$^{2®}$ (K983831), VectorVision® Spine Software (K981508), Vector Vision® CT/Fluoro (K010968

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2003

Mr. Rainer Birkenbach
Executive Vice President
BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany

Re: K024192
Trade/Device Name: VectorVision Fluoro3D
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: April 2, 2003
Received: April 8, 2003

Dear Mr. Birkenbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K024192

Device Name: VectorVision Fluoro3D

Indications For Use:

BrainLAB VectorVision® Fluoro3D is intended to be an intraoperative image guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative image data being processed by a VectorVision workstation. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-ray or MR based model of the anatomy.

Example procedures include but are not limited to:

Spinal Procedures:
- Spinal implant procedures such as pedicle screw placement.

Miriam C. Provost

**(Division Sign-Off)**
**Division of General, Restorative and Neurological Devices**

**510(k) Number** K 024192

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format I-2-96)